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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,044	04/30/2002	Mathias Stecker	2447-015	5502

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,044	Applicant(s) STECKER ET AL. CLO	
	Examiner <i>Carl H. Layno</i> Carl H. Layno 8/30/04	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 30 April 2002.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 5-9 is/are allowed.

6) ☒ Claim(s) 1-4 and 10 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 30 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/3/01</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a 371 of PCT/AU00/01019, filed August 28, 2000, based upon Australian Patent Application PQ 2499, filed August 27, 1999.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on December 3, 2001.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show Figures 9 and 10 as described on p.9 of the specification (lines 2 and 4). Only Figures 1-8 have been submitted.

Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from

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the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

-p.3, line 29, the subtitle "Description" should be changed to "BRIEF DESCRIPTION OF THE DRAWINGS" as per 37 CFR 1.77(b),

-p.4, lines 11-12, under the heading "Description", the brief descriptions for Figures 9 and 10 are missing even though these have been referred to in the specification (p.9, lines 2 and

4). Note that no drawing figures for Figures 9 and 10 have been submitted.

-p.4, line 12, after the brief description of the figures, the subtitle "DETAILED DESCRIPTION OF THE INVENTION" should be inserted. As written, this subtitle is missing. It should precede applicant's written description as per 37 CFR 1.77(b).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: implanted electrodes, circuits for providing a set of electrical stimuli at different stimulus levels, circuits for receiving evoked stimuli, and circuits for calculating a value relating to stimulus levels and corresponding evoked responses. As currently written, claim 10 does not positively recite any structural features. Only a preamble is present.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al '863 (Applicants' prior art).

The Carter et al '360 PCT patent, cited by the applicant as prior art, describes a cochlear system (Fig. 1) employing a stimulating lead 5 having an array of a plurality of electrodes 20 (Fig. 2). Electric stimuli are applied to each electrode/channel 43,54 (Fig. 4) to obtain an evoked action potential (EAP) 44,48, which is evaluated. A resulting "Delta" variable is calculated and compared to a threshold condition 49 (Fig. 4) to determine if any adjustments in stimulus level are necessary (col. 7, lines 18-65). From this calculation is derived a "T-level value" for each channel, which corresponds to stimulus levels necessary to definitely elicit an EAP response (see Fig. 3 and p. 9, lines 25-32).

8. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Maltan '185.

The Maltan '185 patent also recites an implantable cochlear system (ICS) 14 (Fig. 1) equipped with an implanted cochlear electrode array 16. The Maltan system appears to perform all of applicant's claimed method steps. See Fig. 4. It provides a series of stimuli to each electrode 104, measures myogenic evoked responses (MER) 106 to each stimuli, adjusts stimulus energy levels for each electrode 110, and calculates loudness level values for each electrode stimulation pair 112a.

Allowable Subject Matter

9. Claims 5-9 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 5 describes a method for determining the relative responsiveness of electrodes in a multi-electrode intra-cochlear prosthesis including the unique step of “determining the relative responsiveness of the electrodes by comparing the values of step (b) for the tested electrodes”. The prior art references fail to teach this step. Specifically, Carter et al ‘360 compares the responses of its evoked potentials with a preset threshold rather than to the performance of other electrode channels. The other references of record similarly adjust stimulation outputs for each cochlear electrode but fail to perform a comparative test between responses received at different electrodes. As a result, the Examiner deems this claim and its depending claims to be allowable.

11. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a). **New formal drawings for Figures 9 and 10 are now required.**

Conclusion

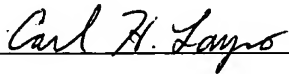
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every

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other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO
PRIMARY EXAMINER

CHL
8/30/2004